O.I.P.E. JC42 MAR 20 2003 PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Roopenian, Derry		Attorney Docket No.	JMY-P01-002
Serial No:	09/993,322		(formerly JL-2010)
Filed:	November 6, 2001	Art Unit:	1632
For:	FcRn-Based Therapeutics for the Treatment of Auto-Immune Disorders	Examiner:	Qian, J. Li

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March 13, 2003
Date of Signature and of Mail Deposit

Crena Soldano
Crena Soldano

Commissioner for Patents
Washington, D.C. 20231

REPLY TO RESTRICTION REQUIREMENT

Madam:

This is a Reply to the outstanding Restriction Requirement, mailed from the U.S. PTO on January 13, 2003, in connection with the above application. Applicants respectfully request a one-month extension of time to respond to the Office Action. A separate Petition for Extension of Time, with authorization to charge the necessary fees, is being filed concurrently. Applicants hereby elect with traverse Group VIII (claims 30, and 47-64), drawn to a method to identify an inhibitor of FcRn-mediated protection of IgG antibodies or to identity a candidate agent for FcRn-mediated drug delivery in an individual using an FcRn-/-, and huFcRn+ knockout-transgenic mouse. Applicants traverse the restriction requirement for the reasons which follow.

Applicants respectfully submit that Groups I, III, IV, V, and VIII are closely related in nature as they encompass overlapping subject matter, namely transgenic mice with homozygous disruption in the endogenous FcRn gene. In particular, Applicants note that it appears that the search for Groups I, III, IV, V, and VIII would be co-extensive. Indeed, all these five groups are classified in Class 800, and Groups III, IV, V, and VIII belong to the same subclass 4. Thus, it

appears that a search covering the subject matter of Group VIII would cover the subject matter of Groups I, III, IV, and V as well. Applicants further note that according to MPEP §803, two criteria must be met for a proper restriction requirement: a) the inventions must be independent or distinct as claimed; and b) there must be a serious burden on the Examiner if restriction is required. Applicants respectfully submit that the Examiner has not shown that there would be a serious burden in simultaneously examining Groups I, III, IV, V, and VIII. Accordingly, reconsideration and withdrawal of the restriction requirement is respectfully requested.

At page 5 of the Office Action, the Examiner states: "[I]nvention group VIII comprises species of trackable composition and different types of animals, i.e. adult, fetus, or neonate. If one of the groups VII or VIII is elected, further election of a species is necessary." This requirement is not clear to Applicants' Attorney, who discussed it with Examiner Li. It is Applicants' Attorney's understanding that election of a species of animal type and a species of candidate agent (not trackable composition) is required. Applicants hereby provisionally elect, and for search purposes only, the following species: 1) adult animal, as one species from the animal type group; and 2) a candidate agent derived from an immunoglobulin Fc region (see claims 48, 53, 58, and 62), as one species from the candidate agent group. Further, as requested by the Examiner, Applicants hereby list claims 1-6, 14-23, 27, 29-30, and 43-80 as being readable on the elected species.

In conclusion, claims 1-80 constitute the pending claims in the present application, and Applicants elect with traverse Group VIII. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should any additional extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945.**

Respectfully Submitted,

Date: March 13, 2003

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